In re Application of: Andy Wolff et al
Serial No.: 10/668,274
Filed: September 24, 2003
Office Action Mailing Date: January 17, 2008

Examiner: Elizabeth McNeill
Group Art Unit: 3767
Attorney Docket: 26486

REMARKS

Reconsideration of the above-identified application in view of the remarks following is respectfully requested.

Claims 1-18, 20, 25-45, 47, 52-54 and 111-113 are in the Application.

Claims 1-18, 20, 25-45, 47 and 52-54 and 111-113 have been rejected under 35 U.S.C. 103.

The claims are rejected under two combinations of references: Sakuma and Pfeiler and Cournut and Pfeiler.

Both Sakuma and Cournut teach dental devices, but do NOT teach an electronic drug release mechanism.

Pfeiler teaches an electronic drug release mechanism, but does NOT teach a dental device.

Applicants contend that the fact that the examiner did not find any reference that suggests a dental device with an electronic drug release mechanism is not a mere coincidence.

It is respectfully submitted that the oral cavity and the outer surface of oral mucosa are open and unprotected environments, and therefore are much more hostile to electronic drug release systems than the protected and closed interior of any tissue, to which an implant outlets drug. Therefore, a person of ordinary skill in the art of dentistry will predict that an oral device as claimed is prone to fail, and to end up with no favorable results.

Thus, Pfeiler, who discusses an electronic drug release mechanism for releasing insulin, is irrelevant to the problems that the oral cavity poses to electronic drug release systems. Therefore, the success expectations of a skilled person of incorporating Pfeiler's electronic drug release into Sakuma or Cournut would be extremely small.

In re Application of: Andy Wolff et al
Serial No.: 10/668,274
Filed: September 24, 2003
Office Action Mailing Date: January 17, 2008

Examiner: Elizabeth McNeill
Group Art Unit: 3767
Attorney Docket: 26486

Some difficulties that a killed person would expect cause an electronic drug release mechanism to fail if incorporated in a dental device of the kind taught by Sakuma or Cournot include:

1. An oral device is expected to suffer from mastication forces. While the drug release mechanisms of Sakuma or Cournut can survive some mechanical deformation, an electronic drug release as claimed is prone to suffer from short circuit, conductors tearing, or other electronic failures even if only slightly deformed.

2. The oral cavity is unique in the amount and variety of bacterial flora it contains. According to the book "Clinical Methods: the History, Physical and Laboratory Examinations" by H. Kenneth Walker, W. Dallas Hall, Publisher: Butterworth-Heinemann, 3rd ed. 1990, pages 619-620, "The peculiarities of the oral cavity are unique. No other body cavity ... contains bacterial flora in the amount or variety encountered in the normal human mouth". This bacterial flora is known in the art to short electrical circuits of electrical devices.

3. The oral cavity goes under extreme and abrupt temperature changes. The temperature at the oral cavity usually varies from about the freezing point (for instance, when the patient eats ice-cream) to about 55°C (for instance, when the patient drinks hot tea). The temperature changes from body temperature to 0°C or 55°C are very abrupt.

Electronic drug release systems are usually not made to operate under such extreme and abrupt temperature changes, and are prone to fail under such conditions.

4. Extreme and abrupt pH changes. The pH at the oral cavity usually varies from dramatically between, for instance, when the person drinks Coca Cola and when the person chews anti-gastric tablets. The pH in the oral cavity usually changes from about 2 to about 10, and such changes may happen very abruptly.

Electronic drug release systems are usually not made to operate under such extreme and abrupt pH changes, and are prone to fail under such conditions.

In summary, the applicants respectfully submit that it would have not been obvious to a person of ordinary skill in the art to combine the teachings of Sakuma or

In re Application of: Andy Wolff et al
Serial No.: 10/668,274
Filed: September 24, 2003
Office Action Mailing Date: January 17, 2008

Examiner: Elizabeth McNeill
Group Art Unit: 3767
Attorney Docket: 26486

Cournut with the teachings of Pfeiler so as to replace the drug release mechanisms of the former ones with that of the latter.

In summary, applicants submit that, as taught by the above-referenced textbook of Walker and Hall "*The peculiarities of the oral cavity are unique. No other body cavity shares such a close relationship to the external environment, represents as many varied and functional anatomical entities, or contains bacterial flora in the amount or variety encountered in the normal human mouth*". In fact, the peculiarities of the oral cavity are so unique, that dentistry is a discipline separate from medicine, and a medical doctor cannot become a dentist without extensive studies. The same is true for a dentist that wants to become an MD.

In the case of the present claims, this difference between the two disciplines is pronounced in that Pfeiler's device is unsuitable for use in the mouth, simply because an electronic drug delivery system must be designed especially for dentistry, if it is to be of any use in dentistry.

Applicants now turn to discuss each of the rejections on its own merits.

Independent claim 1

Sakuma and Pfeiler

Claim 1 is rejected as being unpatentable over Sakuma et al (US 5,584,688, hereinafter Sakuma) in view of Pfeiler et al (US 5,558,640, hereinafter Pfeiler). Applicants respectfully traverse.

Not all the claim limitations were considered

Independent claim 1 contains a limitation that the device comprises "an electronic drug release mechanism, configured for providing said controlled drug release into one or both of an oral cavity of a subject and an outer surface of an oral mucosa of a subject".

The Examiner did not consider this limitation in the Office Action.

Applicants respectfully contend that in formulating an obviousness rejection all the claim limitations must be considered. (See MPEP 2143.03)

In re Application of: Andy Wolff et al
Serial No.: 10/668,274
Filed: September 24, 2003
Office Action Mailing Date: January 17, 2008

Examiner: Elizabeth McNeill
Group Art Unit: 3767
Attorney Docket: 26486

Therefore, applicants respectfully submit that no *prima facie* case of obviousness set forth by the Examiner.

At least one limitation is not taught by any of the cited references

Independent claim 1 contains a limitation that the device comprises "an electronic drug release mechanism, configured for providing said controlled drug release into one or both of an oral cavity of a subject and an outer surface of an oral mucosa of a subject". Applicants respectfully submit that this limitation is not taught by Sakuma, neither by Pfeiler.

The Examiner states that Sakuma does not teach an electronic release mechanism.

Applicants agree. However, it is respectfully submitted that Sakuma's drug release mechanism is also not "configured for providing said controlled drug release into one or both of an oral cavity of a subject and an outer surface of an oral mucosa of a subject", as claimed.

Sakuma discloses an implant implanted ***under*** the gingiva, for injecting drug ***into*** the gingival.

The Examiner states that Pfeiler teaches an implantable element with electronic drug release mechanism. However, Pfeiler's drug release mechanism, similarly to Sakuma's, is also not "configured for providing said controlled drug release into one or both of an oral cavity of a subject and an outer surface of an oral mucosa of a subject". Pfeiler refers to injecting insulin, and is completely silent regarding any dental configuration.

Thus, the above-cited limitation is not taught by any of the cited references.

Applicants respectfully refers the Examiner to *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974), which until recently was cited in MPEP 2143.03, according to which, to establish prima facie obviousness of a claimed invention, all the claim features must be taught or suggested by the prior art.

In re Application of: Andy Wolff et al
Serial No.: 10/668,274
Filed: September 24, 2003
Office Action Mailing Date: January 17, 2008

Examiner: Elizabeth McNeill
Group Art Unit: 3767
Attorney Docket: 26486

Combining Sakuma and Pfeiler would not result in the claimed invention

Both Sakuma and Pfeiler teach implantable devices. These implantable devices are configured to outlet the drug into the closed and protected environment of the tissue near the implant, and not to outlet the drug to the open and unprotected oral cavity or to the similarly open and unprotected outer surface of oral mucosa, as claimed. Therefore, Applicants submit that combining Sakuma and Pfeiler cannot result in an oral device as claimed.

Thus, Applicants respectfully submit that the combination of Sakuma and Pfeiler does not teach all the limitations of claim 1, and that a *prima facie* case of obviousness was not set forth by the Examiner.

Cournut and Pfeiler

Claim 1 is rejected as being unpatentable over Cournut in view of Pfeiler. Applicants respectfully traverse.

Not all the claim limitations were considered

Independent claim 1 contains a limitation that the device comprises "an electronic drug release mechanism, configured for providing said controlled drug release into one or both of an oral cavity of a subject and an outer surface of an oral mucosa of a subject".

The Examiner did not consider this limitation in the Office Action.

Applicants respectfully contend that in formulating an obviousness rejection all the claim limitations must be considered. (See MPEP 2143.03)

Therefore, applicants respectfully submit that no *prima facie* case of obviousness was set forth by the Examiner.

At least one limitation is not taught by any of the cited references

Independent claim 1 contains a limitation that the device comprises "an electronic drug release mechanism, configured for providing said controlled drug release into one or both of an oral cavity of a subject and an outer surface of an oral

mucosa of a subject". Applicants respectfully submit that this limitation is not taught by Cournut, neither by Pfeiler.

The Examiner states that Cournut does not teach an electronic release mechanism. Applicants agree. However, Applicants also submit, as explained above, that Pfeiler's mechanism is not "configured for providing said controlled drug release into one or both of an oral cavity of a subject and an outer surface of an oral mucosa of a subject". Pfeiler refers to injecting insulin, and is completely silent regarding any dental configuration, and, as explained and reiterated above, this drug release system is not suitable to work under the harsh conditions in the oral cavity.

Thus, an electronic drug release mechanism configured as claimed is not taught by any of the cited references.

Applicants respectfully submit that the combination of Cournut and Pfeiler does not teach all the limitations of claim 1, and that no *prima facie* case of obviousness was set forth by the Examiner.

Combining Cournut and Pfeiler would change the principles of operation of Cournut

Cournut teaches a slow-release dental device, where the active ingredient slowly dissolves into the saliva when the device is moistened. Replacing it with an electronic drug release mechanism as suggested by the Examiner will change the operational principles of the device; and therefore cannot render the combination *prima facie* obvious. (See MPEP 2143.01 VI: "the proposed modification cannot change the principle of operation of a reference".)

Independent claim 28

Independent claim 28 contains a limitation that the method comprises providing "an electronic drug release mechanism, configured for providing said controlled drug release into one or both of an oral cavity of a subject and an outer surface of an oral mucosa of a subject".

In re Application of: Andy Wolff et al
Serial No.: 10/668,274
Filed: September 24, 2003
Office Action Mailing Date: January 17, 2008

Examiner: Elizabeth McNeill
Group Art Unit: 3767
Attorney Docket: 26486

This limitation is similar to the limitation discussed in the context of claim 1, and accordingly, Applicants respectfully submit that claim 28 is patentable over the cited art for at least the same reasons as claim 1 is.

Independent claim 113

Independent claim 113 is rejected under Section 103 as being unpatentable over Cournut in view of Pfeiler. Applicants respectfully traverse.

Independent claim 113 contains a limitation that the method comprises "anchoring an electronic drug release mechanism to the outer surface of the oral mucosa of the patient". Applicants respectfully submit that none of the prior art describes anchoring an electronic drug release mechanism to the outer surface of the oral mucosa of the patient.

Cournut does not describe anchoring ***an electronic*** drug release mechanism anywhere.

Pfeiler does not describe anchoring an electronic drug release ***to the outer surface*** of any tissue.

Applicants respectfully submit that the uniqueness of the oral cavity, discussed at the outset of this response, makes it non-obvious to modify Cournout to include Pfeiler's drug release mechanism, because it would require "a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate." (see MPEP 2143.01 VI, citing *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)).

Thus, Applicants submit that the common sense of a person skilled in the art of dentistry would tell him that there is very little chance of success in taking electronic drug release mechanisms designed to be implanted, and anchoring them on the outer surface of the oral mucosa.

In re Application of: Andy Wolff et al
Serial No.: 10/668,274
Filed: September 24, 2003
Office Action Mailing Date: January 17, 2008

Examiner: Elizabeth McNeill
Group Art Unit: 3767
Attorney Docket: 26486

New independent claim 114

New independent claim 114 contains the limitation the device comprises "an electronic drug release mechanism, suitable for functioning at the conditions inside the oral cavity".

Applicants respectfully submit that none of the cited references describes such a drug release mechanism. The only electronic drug release mechanism of record is taught by Pfeiler, and this is not specially made for use in the oral cavity, and therefore is deemed to be unsuitable for working in the oral cavity, as discussed at the outset of the present response.

Dependent claims 2-18, 20, 25-27, 29-45, 47, 42-52, 111, 112, 115 and 116

The dependent claims are patentable at least in virtue of being dependent on patentable base claims.

However, applicants wish to draw the Examiner's attention to claim 5, which is patentable over claim 1.

Claim 5 contains the limitation that the oral device comprises "at least one local sensor, integrated with said device". Applicants respectfully submits that the local sensor of the claim is "local" inside the oral cavity, and therefore, should be operable in a wide temperature range (as one example), of between 0 to 55°C. The sensors taught by Pfeiler, cited by the Examiner, are not local to the oral cavity, but rather implanted or external to the body. Inside the tissue, temperature is usually between 36°C and 42°C, and outside the body temperature does not change as abruptly as inside the mouth. Pfeiler does not teach sensors operable in the wide temperature range implicitly required by the claim. Similarly, Pfeiler does not teach a sensor operable in a broad pH range as may be expected in the mouth, or under mastication forces as may be expected in the mouth. Thus, a skilled person would not expect any success by modifying Sakuma or Cournout to include sensors as taught by Pfeiler.

Claim 115 contains the limitation that the oral device has "a portion that faces a biting surface a tooth". None of the cited art show a device with a surface facing a

biting surface of a tooth. Sakuma is implanted under the gingiva, and Cournut's device has only surfaces that face the cheek, lips, or tongue. Pfeiler's device is not oral. Thus, this claim contains an additional limitation not described or suggested in any of the cited references.

Claim 116 contains a limitation that the oral device of claim 1 has "a hard outer shell". None of the cited references teaches or suggests such a shell. Claim 117, which contains the limitation that the outer shell is perforated, is even more remote from any of the cited art.

In view of the above remarks it is respectfully submitted that claims 1-18, 20, 25-45, 47, 52-54, and 111-113 are now in condition for allowance. A notice of allowance is respectfully solicited.

Respectfully submitted,

Martin D. Moynihan
Registration No. 40,338

Date: May 19, 2008

Enclosures:

- Petition for Extension (One Month)
- Additional Claims Transmittal Fee